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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/995,130	11/27/2001	David B. MacLean	PCI1088ATMC	9834

7590

03/25/2003

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EXAMINER

BAHAR, MOJDEH

ART UNIT

PAPER NUMBER

1617

DATE MAILED: 03/25/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/995,130

Applicant(s)

MACLEAN, DAVID B.

Examiner

Mojdeh Bahar

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-60 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-60 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Election/Restrictions***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-10, 31-45 drawn to a method of treating different androgenic conditions comprising administering an estrogen agonist/antagonist of formula I and testosterone, classified in class 514, subclasses 171, 277, 278, 359, 508, for example.
- II. Claims 11-30, drawn to a method of treating different cardiovascular conditions comprising administering an estrogen agonist/antagonist of formula I and testosterone, classified in class 514, subclasses 171, 277, 278, 359, 508, for example.
- III. Claims 46-50, drawn to a method of treating osteoporosis comprising administering an estrogen agonist/antagonist of formula I and testosterone, classified in class 514, subclasses 171, 277, 278, 359, 508, for example.
- IV. Claim 51 (in part), drawn to a method of treating different androgenic conditions comprising administering an estrogen agonist/antagonist and testosterone, classified in class 514, subclasses 171, for example.
- V. Claim 51 (in part), drawn to a method of treating different cardiovascular conditions comprising administering an estrogen agonist/antagonist and testosterone, classified in class 514, subclasses 171, for example.

- VI. Claim 51 (in part), drawn to a method of treating osteoporosis comprising administering an estrogen agonist/antagonist and testosterone, classified in class 514, subclasses 171, for example.
- VII. Claim 52 (in part), drawn to a method of treating different androgenic conditions comprising administering an estrogen agonist/antagonist of formula V or VI and testosterone, classified in class 514, subclasses 171, 415 for example.
- VIII. Claim 52 (in part), drawn to a method of treating different cardiovascular conditions comprising administering an estrogen agonist/antagonist of formula V or VI and testosterone, classified in class 514, subclasses 171, 415 for example.
- IX. Claim 52 (in part), drawn to a method of treating osteoporosis comprising administering an estrogen agonist/antagonist and testosterone of formula V or VI and testosterone, classified in class 514, subclasses 171, 415 for example.
- X. Claim 53 (in part), 54-58, drawn to a kit comprising an androgen/agonist antagonist of formula I and testosterone, classified in class 514, subclasses 171, 277, 278, 359, 508, for example.
- XI. Claim 53 (in part), and 59, drawn to a kit comprising an androgen/agonist antagonist listed in the claim and testosterone, classified in class 514, subclasses 171, for example.
- XII. Claim 53 (in part), and 60, drawn to a kit comprising an androgen/agonist antagonist of formula V or VI and testosterone, classified in class 514, subclasses 171, 415 for example.

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Inventions X and I-III; XI and IV-VI; XII and VII-IX are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case cardiovascular diseases can be treated by HMG CoA reductase inhibitors, calcium channel blockers, diuretics, etc. Some androgen related diseases can be treated by the administration of testosterone alone, and osteoporosis can be treated by alendronate or calcium.

Inventions I-IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions functions or different modes of operation.

#### **Specie Election**

Claims 1-60 are generic to a plurality of disclosed patentably distinct species comprising different cardiovascular, andropause related conditions/diseases. **Applicant is required under 35 U.S.C. 121 to elect a single disclosed species (i.e., atherosclerosis), even though this requirement is traversed.** The treatment of each of the cardiovascular diseases and each of the andropause-related conditions represents a separate field of medical technology having a separate field of search. The search for treatment of all andropause-related diseases and cardiovascular disorders is therefore an undue burden on the office. Note that the search is not limited to patent files.

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Claims 1-60 are generic to a plurality of disclosed patentably distinct species comprising (a) formula I compounds; (b) formula V and VI compounds (c) compounds enumerated in claim 51.

These claims encompass species that are so diverse and unrelated structurally that a reference anticipating one of the species would not anticipate or render obvious the other species. Thus, the stated species are capable of supporting separate patents. To illustrate this diversity, consider the following. The many different structures encompassed by the generic formula I can be classified in many different subclasses of class 514: 171, 277, 278, 359, 508, 169, 415 are just a few of these subclasses. Therefore, the diversity of species in claims 1-60 requires a search of many different subclasses, 171, 277, 278, 359, 508, 169, 415, etc., which constitutes an undue burden to the office. Applicant is advised that the response to this requirement must include an identification of the species that is consonant with the requirement set forth in 35 U.S.C. 121 as well as a listing of all claims readable thereon. **Applicant is required to elect a single specie for examination purposes. The SPECIE is a compound wherein all of the substituents are particularly named.**

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that in order for the reply to this requirement to be complete

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it must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).


Because the above restriction/election requirement is complex, a telephone call to the applicant's agent to request an oral election was not made. See M.P.E.P. Sec 812.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mojdeh Bahar whose telephone number is (703) 305-1007. The examiner can normally be reached on (703) 305-1007 from Monday to Friday from 9:00 a.m. to 5:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreeni Padmanabhan, can be reached on (703) 305-1877. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4556.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Mojdeh Bahar  
Patent Examiner  
March 21, 2003

  
SREENI PADMANABHAN  
PRIMARY EXAMINER  
3/24/03